REMARKS

This amendment is responsive to the non-final Office Action mailed April 4, 2007 in relation to the above-identified application wherein the Examiner indicated that the present application incorrectly identified the parent application as Serial No. 10/466,330 in the cross-reference section of paragraph 0001.

By this amendment, Application has amended paragraph 0001 of the present application to correct the identity of the parent application (Serial No. 10/465,330) for the present application.

In the Office Action, Claims 11-15 and 21-23 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over Claims 11-15 and 21-23 of co-pending Application Serial No. 10/465,330.

By this amendment, Claims 11-15 and 21-23 of the present application have been cancelled such that the double patenting rejection advanced thereagainst is now moot.

In the Office Action, Claims 1-26 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-17 of co-pending Application Serial No. 10/841,594. Claims 1-9 and 16-17 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over Claims 19-20, 35 and 49-52 of co-pending Application Serial No. 09/733,455. The Examiner indicated that the above-noted double-patenting rejections can be overcome by the filing of a terminal disclaimer.

By this amendment, submitted herewith is a terminal disclaimer in compliance with 37 CFR 3.73(b) such that the above-mentioned obviousness-type, double patenting rejections advanced by the Examiner in relation to Serial Nos. 10/841,594 and 09/733,455 are now believed to be overcome.

In the Office Action, Claims 1-26 were rejected under 35 U.S.C. 102(e) as being anticipated by Beyar (U.S. Patent No. 6,334,446).

By this amendment, Applicant has revised independent Claims 1 and 16 to more clearly define the subject matter which Applicant regards as the invention and which is believed to distinguish over the cited prior art, namely, Beyar, for reasons discussed in detail below.

Summary of Claim Amendments

In the present amendment, Applicant has cancelled Claims 11-15 and 21-26. In addition, Applicant has amended Claims 1 and 16 to clarify Applicant's invention and to distinguish over the prior art references cited thereagainst. Claims 8 and 19 have been amended to provide consistent nomenclature throughout the claims.

New Claims 27-34 have been added to further clarify several features of the present invention. Claim 27 is directed toward an embodiment of the anchor mechanism having at least one barbed portion extending outwardly from a cord and having mesh material extending aftwardly along the cord of the barbed portion.

Support for new Claims 27-34 is found generally in Figs 16, 22A-22B and 24-26 and in paragraph [0128] which discloses that the "barbed portion 904 will be configured as per any of the aforementioned embodiments such that the barb 904 will be operative to be inserted into a mass of soft tissue into a first direction but resist rearward movement when pulled in the opposite direction." (Spec., Para. [0128]).

Support for the specific configurations of the anchor mechanisms claimed in Claims 27-34 is provided in paragraph [0103] of the application as filed which discloses that "the anchor mechanism comprises a plurality of anchor bodies 840 each having opposed, outwardly extending anchor members or arms 842 which thus define a generally Y-shaped body. Each respective anchor mechanism 840 is disposed upon elongate cord 844." (Spec., Para. [0103]).

Paragraph [0103] of the application further discloses that "Each respective anchor mechanism 840 is disposed upon elongate cord 844, which may take the form of a suture or other implantable material well-known to those skilled in the art. To facilitate the ability to manipulate anchor mechanism 808, elongate cord 844 may be formed to have a desired stiffness, and may be formed as a cable having reinforced material therein operative to provide some structural rigidity as may be desired in some applications." (Spec., Para. [0103]).

Support for the specific configuration of the cord is found in paragraph [0104] of the specification which discloses that "dual-pronged anchor mechanisms [may be] disposed linearly about a cord-like suture of various malleability to thus enable the same to advance through tissue in one direction, either by pushing or pulling, but resist rearward movement in an opposite direction." (Spec., Para. [0104]).

Support is also found in Paragraph [0094] of the specification as filed which discloses that "the anchor mechanisms 808a, 808b, may be provided with ... materials to facilitate the ingrowth of tissue about the same to thus enable the anchor mechanisms to remain firmly seated into position once implanted into the body. Illustrative of such an embodiment would include the use of a mesh material cut such that the strands of the fabric of such mesh facilitate movement when advanced in a first direction but resist rearward movement due to the frayed, outwardly-flaring strands of the mesh that would be oriented to cause such loose ends to resist or become biased against rearward movement." (Spec., Para. [0094]).

Based upon the above-mentioned support for new Claims 27-34 provided by the specification as originally filed, Applicant submits that no new matter is added.

Traversal of Rejection of system Claim 1 under 35 USC § 102(e) in view of Beyar

Applicant has amended independent Claim 1 in order to clarify that the anchor mechanisms are specifically configured to be advanced into and become engaged within soft tissue. In this regard, Applicant wishes to emphasize that ***the anchor mechanisms as claimed in Claim 1 are specifically configured to be "resistant to movement in an opposite direction in the soft tissue."*** Furthermore, Applicant wishes to emphasize that ***the anchor mechanisms as claimed in Claim 1 are "configured to become permanently fixed in position within the soft tissue."***

As disclosed in the application as originally filed, the anchor mechanisms used in connection with the systems of the present invention are configured to "become positioned or embedded within a target site of tissue such that the same can become resident or fixed in position. In this regard, it is contemplated that the anchor mechanisms ... may be provided with a textured surface or may otherwise be provided with materials to facilitate the ingrowth of tissue about the same to thus enable the anchor mechanisms to remain firmly seated into position once implanted into the body." (Specification, Paragraph [0094]) As also disclosed in Paragraphs [0093] – [0095] of the application and as depicted in Figure 22, the implantable sling remains in the desired position due to the ability of the anchoring mechanisms to remain seated within the soft tissue such as the pubocervical fascia or the obturator membrane.

In contrast, the bone anchors disclosed in the Beyar reference are understood to be exclusively configured to be engaged within bone and are not understood to be configured to become engaged within soft tissue nor are the bone anchors of Beyar understood to be configured so as to be resistant to movement in soft tissue.

For example, the system described in Kovac expressly discloses and illustrates bone anchors that are configured to be affixed to the posterior/inferior pubic bone. (Figs. 23-45; Col. 3, lines 7-13; and Abstract) Furthermore, Beyar expressly indicates that the devices and systems disclosed therein are directed toward providing improved devices for inserting a bone anchor into position. (Col. 4, lines 48-50 - "Accordingly, it is an object of the present invention to provide an insertion device which minimizes recoil during ejection of a bone anchor into bone."). Beyar also expressly indicates that the anchor mechanism (indicated by reference numeral 14 in Fig. 1 of Beyar) and the deployment mechanism for installing the anchor mechanism 14 "relate to an improved inserter device (whether a stapler or screw insert) for inserting a bone anchor ... into a patient"). (Col. 10, lines 27-30)

Accordingly, Applicant submits that Beyar fails to anticipate the invention as claimed in Claim 1 insofar as the anchor mechanisms of the present invention are configured to secure a sling into position in soft tissue and to be non-movably fixable within soft tissue only and not bone. Because Beyar fails to teach, suggest or even imply that the bone anchors are configured to be insertable within and non-movably retained in soft tissue, the rejection of Claim 1 under 35 U.S.C. § 102 is believed to be overcome. As such Claim 1, as well as all claims depending therefrom, namely, Claims 2-10 and 27-30, are also believed to be allowable for at least the same reasons.

Traversal of Rejection of method Claim 16 under 35 USC § 102(e) in view of Beyar

Applicant has amended independent Claim 16 in order to clarify that the deployment mechanism for installing the anchor mechanisms is "***a non-mechanically assisted deployment mechanism***" which lacks the mechanical spring(s) or air-pressure means which Beyar uses to force bone anchors (i.e., the alleged equivalent of Applicant's soft tissue anchor mechanisms) into pubic bone. In this regard, Applicant wishes to emphasize that the deployment mechanism of Applicant's invention comprises a "***manually operable handle***" having ***"an actuator mounted on a shaft [that is] axially moveable within [a] deployment member."***

Applicant further wishes to emphasize that the deployment mechanism claimed in Claim 16 is configured for manual insertion (i.e., non-mechanically assisted insertion) of the anchor mechanisms into tissue. (Specification, Figs. 20-20B and Para. [0089]) In this regard, the deployment mechanism as claimed in Claim 16 is adapted to install the anchor mechanisms using only manually-supplied force (e.g., by a physician depressing the actuator while grasping the handle). Because the actuator is directly connected to the shaft, manually depressing the shaft induces axial translation or axial movement of the shaft within or along the deployment member and thereby forces the anchor mechanism into the soft tissue at the target site. (Specification, Para [0089]).

In contrast, ***Beyar discloses the use of mechanical means such as mechanical springs and/or air pressure and/or battery power to drive the bone anchors into pubic bone***. More specifically, Beyar discloses "a drive mechanism and a trigger to activate the drive mechanism; ... an ejector driven by the drive mechanism, movable in the barrel for ejecting a staple..." (Col. 4, ll 2-7). ***Beyar further discloses that the "bone anchor inserter...is operated either by an impact or by a rotational movement to insert a staple or screw into the bone..."*** (Col. 5; ll 37-40). Further examples of the mechanically-assisted configuration of ***Beyar include a "stapler device [which] may be pneumatically powered"*** wherein "air pressure supplied from the pressurized air tube ... applies an air pressure pulse to ejector pin 16 to cause it to impact against the base of staple 14 and thereby to eject the staple." (Col. 9; ll 8-21 and Fig. 1).

In a further embodiment illustrating the mechanical-assisted means required in Beyar for inserting bone anchors into pubic bone, ***Beyar discloses "An internal spring mechanism ... providing the forcible ejecting, pushing and implanting of the bone anchor ... into bone."*** (Col. 10; ll 58-65). Beyar indicates that the "spring mechanism stores the mechanical energy necessary to eject and insert the anchor into bone" (See Col. 11; ll 15-18) and that the "inserter has a dual spring mechanism which allows the user to impart more energy and impact to the anchor during implantation into the bone." (Col. 11; ll 52-54 and Fig. 11). In yet another embodiment further illustrating the mechanical-assisted means required in Beyar for inserting bone anchors into pubic bone, ***Beyar discloses that "inserter ... having an internal battery 875, a battery-operated rotating motor 881,*** with a finger switch 880 to control operation." (Col. 11; ll 22-25 and Fig. 12c).

Based upon the above, Applicant submits that Beyar fails to anticipate the above-noted features of Applicant's invention as claimed in amended Claim 16. More specifically, ***Beyar fails to anticipate the feature of Applicant's invention being configured as a non-mechanically assisted deployment mechanism.*** As such, amended Claim 16 is believed to distinguish over Beyar such that Claim 16 is believed to be allowable. Furthermore, all claims depending from Claim 16, namely, Claims 17-20 and 31-34, are also believed to be allowable for at least the same reason.

Conclusion

Accordingly, Applicant respectfully submits that as amended herein, Claims 1-10, 16-20 and 27-34 are distinguished over the cited art and are therefore believed to be in condition for allowance. Entry of the amendments and issuance of a Notice of Allowance is therefore respectfully requested. Should the Examiner have any suggestions for expediting the allowance of the application or requires additional information or has any suggestions how to resolve any outstanding issues, please contact Applicant's representative at the telephone number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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